JUL 17 2003

K031650

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3544

Contact Person: Kay A. Taylor

Date Prepared: May 27, 2003

Device Name

Proprietary name: Ferritin Generation 2

Common name: Ferritin

Classification name: Ferritin, Antigen, Antiserum, Control

Device Description

A particle enhanced immunoturbidimetric assay in which human ferritin agglutinates with latex particles coated with anti-ferritin antibodies. The precipitate is determined turbidimetrically at 552 nm.

Intended use

In vitro diagnostic reagent system intended for use on COBAS Integra system for the quantitative immunological determination of human ferritin in serum * and plasma.

Indications for Use

Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism such as hemochromatosis (iron overload) and iron deficiency anemia.

Substantial Equivalence

The Ferritin Generation 2 is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the COBAS Integra Ferritin assay (K963292). Both products are intended for use in the quantitative determination of Ferritin on automated clinical chemistry analyzers.

Substantial equivalence - similarities

The following table compares the Ferritin Generation 2 Assay with the predicate device.

Feature	Ferritin Generation 2	Ferritin (predicate)
Intended Use	In vitro diagnostic reagent system intended for use on COBAS INTEGRA system for the quantitative immunological determination of human ferritin in serum and plasma.	In vitro diagnostic reagent system intended for use on COBAS INTEGRA system for the quantitative immunological determination of human ferritin in serum and plasma.
Indication for Use	For the quantitative determination of ferritin in human serum and plasma. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism such as hemochromatosis (iron overload) and iron deficiency anemia.	For the quantitative determination of ferritin in human serum and plasma. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism such as hemochromatosis (iron overload) and iron deficiency anemia.
Assay Protocol	Particle enhanced Immunoturbidometric	Particle enhanced Immunoturbidometric
Instrument	COBAS Integra Clinical Chemistry Analyzers	COBAS Integra Clinical Chemistry Analyzers
Sample Type	Serum and plasma	Serum and plasma
Formulation	**R**: Glycine buffer stabilized with 0.09% sodium azide, 5mg/ml rabbit globulin in vial B (liquid). **R2**: Latex particles coated with anti-human ferritin (rabbit) in glycine buffer, stabilized with 0.09% sodium azide in vial C (liquid).	**R**: Glycine buffer stabilized with 0.09% sodium azide in vial B (liquid). **R2:** Latex particles coated with anti-human ferritin (rabbit) in glycine buffer, stabilized with 0.09% sodium azide in vial C (liquid).
Calibrator	FERR T Standard	FERR T Standard
Controls	FERR /MYO T Control	FERR /MYO T Control
Reagent Stability	On board: 12 weeks	On-board: 12 weeks

Substantial equivalence – differences

The following table compares the Ferritin Generation 2 Assay with the predicate device.

Feature	Ferritin Generation 2	Ferritin (predicate)
Expected Values	Females: 15-150 ng/ml Males: 30-400 ng/ml (3 mos-16 yrs): 20-200 ng/ml (2^{nd}-3^{rd} month): 80-500 ng/ml (1^{st} month): 150-400 ng/ml (umbilical cord blood): 50-250 ng/ml	Females: 10-120 ng/ml Males: 20-300 ng/ml
Measuring Range	0-382 ng/ml	Integra 400: 0-280 ng/ml Integra 700: 0-300 ng/ml
Traceability / Standardization	Standardized against the NIBSC Reagents for Ferritin (human spleen 80/578).	Traceable to WHO Reference Preparation for Human Liver Ferritin (1^{st} International Standard 1984)
Calibration Interval	After each lot and 84 days	After each lot

Substantial equivalence – performance characteristics

The performance characteristics of the Ferritin Generation 2 Assay and the predicate device are compared in the table below.

Feature	Ferritin Generation 2	Apolipoprotein B (predicate)
Precision	**Within run CV** 9.0% @ 19.8 ng/ml 2.5% @ 107.5 ng/ml **Between Day CV** 7.8% @ 20.3 ng/ml 3.4% @ 157.0 ng/ml	**Within run CV** 9.9% @ 19 ng/ml 1.2% @ 260 ng/ml **Between Day CV** 10.2% @ 19 ng/ml 3.8% @ 260 ng/ml
Method Comparison	Bablok/Passing: Ferritin Generation 2 (Y) / COBAS Integra Ferritin (X). y = 1.30x + 12.98 ng/ml r = 0.922	Bablok/Passing: Ferritin (Y)/ commercially available system (X). y = 0.84x + 0.8 ng/ml r = 0.992
Limitations	• Icterus: No significant interference • Hemolysis: No significant interference up to a level 596 µmol/l. • Lipemia: No significant interference up to an Intralipid level of 160 mg/dL • Rheumatoid factors: No significant interference	• Icterus: No significant interference • Hemolysis: No significant interference • Lipemia: No significant interference • Rheumatoid factors: No significant interference
Prozone Effect	No effect up to 10,000 ng/ml	Integra 400/400 plus: No effect up to 4300 ng/ml Integra 700 /800: No effect up to 45,000 ng/ml
Analytical sensitivity (LDL)	7.5 ng/ml	5 ng/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor, MT (ASCP), RAC
Regulatory Program Principal
Centralized Diagnostic Submissions
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

JUL 17 2003

Re: k031650
Trade/Device Name: Roche COBAS Integra Ferritin Generation 2
Regulation Number: 21 CFR § 866.5340
Regulation Name: Ferritin Immunological Test System
Regulatory Class: II
Product Code: DBF
Dated: July 7, 2003
Received: July 9, 2003

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K031650

Device Name: Ferritin Generation 2 Test System

Indications For Use:

In vitro diagnostic reagent system intended for use on COBAS INTEGRA system for the quantitative immunological determination of human ferritin in serum and plasma.

Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism such as hemochromatosis (iron overload) and iron deficiency anemia.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for J. Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031650